

Attorney Docket No.: 08321-0152 CT1

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re:

Patent application of

Scott A. WALDMAN et al.

Group Art Unit:

Application No.

10/656,895

1614

Filed:

September 5, 2003

Examiner:

Not Yet Assigned

For: COMPOSITIONS THAT SPECIFICALLY BIND

TO COLORECTAL CANCER CELLS AND

METHODS OF USING THE SAME

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

## INFORMATION DISCLOSURE STATEMENT

Sir:

Pursuant to 37 C.F.R. § 1.56 and in accordance with 37 C.F.R. §§ 1.97-1.98, the Applicants attach hereto a completed PTO Form-1449 (modified). This Information Disclosure Statement is being filed after three months following the filing date of this application but before the mailing date of the first Office Action on the merits. Therefore, no fee is believed to be due for this statement. However, authorization is provided to charge any fee deemed to be applicable to this filing to Deposit Account No. 50-0573.

The Examiner is respectfully requested to review the items listed on the attached form and make them of record in the instant application as required by M.P.E.P. §609. It is requested that the Examiner initial the enclosed duplicate substitute PTO Form-1449, and return one copy to the undersigned.

## **CERTIFICATE OF MAILING** UNDER 37 C.F.R. 1.8(a)

I hereby certify that this paper, along with any paper referred to as being attached or enclosed, is being deposited with the United States Postal Service on the date indicated below, with sufficient postage, as first class mail, in an envelope addressed to: Commissioner for Patents. P.O. Box 1450, Alexandria, VA 22313-1450. Kacu

BY:

KAREN M. SPINA

DATE:

February 20, 2004

Pursuant to 37 CFR § 1.98(d), copies of the references listed in the Form PTO-1449 are not enclosed, since this patent application is a continuation of U.S. Application No. 09/649,697, filed August 28, 2000. Copies of the references are contained in the file of the earlier application. The Examiner should contact the undersigned if additional copies of any of the listed references are needed.

This Statement should not be construed as a representation that the cited references are material or that more relevant prior art does not exist.

Respectfully submitted,

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Attorney for the Applicants



Form 1	PTO-1449 Modified	Docket No. 08321-0152 CT1	Serial No. 10/656,895	
C	Patent and Publications Cited by Applicant veral sheets if necessary)	Applicant Scott A. Waldman et al.		
1	epartment of Commerce and Trademark Office	Filing Date 09/05/2003	Group 1614	
ОТНЕ	R DOCUMENTS (Including Autho	r, Title, Date, Pertine	nt Pages, Etc.)	
AA	Adams, R.D., "Anxiety, Depression, Harrison's Principles of Internal Mep. 68		•	
	Alexander et al., "Oncogene alterationitrosourea", Am. J. Med. Sci., 1992,		induced by N-methyl-N-	
1 1 1	Beck-Sickinger et al., "Neuropeptide Y: identification of the binding site", Int. J. Peptide Protein Res., 1990, 36, 522-530			
AD.	Berd et al., "Induction of Cell-mediated Immunity to Autologous Melanoma Cells and Regression of Metastases after Treatment with a Melanoma Cell Vaccine Preceded by Cyclophosphamide", Cancer Res., 1986, 46, 2572-2577			
	Berd et al., "Immunization with Haptenized, Autologous Tumor Cells Induces Inflammation of Human Melanoma Metastases", Cancer Res., 1991, 51, 2731-2734			
1	Blond-Elguindi et al., "Affinity Pann Bacteriophages Reveals the Binding			
AG	Bold et al., "Experimental gene therapy of human colon cancer", Surgery, 1994, 116(2), 189-196			
	Ciardiello et al., "Inhibition of CRIPTO expression and tumorigenicity in human colon cancer cells by antisense RNA and oligodeoxynucleotides", <i>Oncogene</i> , 1994, 9(1), 291-298			
	Collins et al., "c-myc antisense oligonucleotides inhibit the colony-forming capacity of Colo 320 colonic carcinoma cells", J. Clin. Invest., 1992, 89(5), 1523-1527			
AJ	AJ Cooney et al., "Site-Specific Oligonucleotide Binding Represses Transcription of the Human c-myc Gene in Vitro", Science, 1988, 241, 456-459			
EXAMINER		DATE CONSIDER	ED	

Form	PTO-1449 Modified	Docket No. 08321-0152 CT1	Serial No. 10/656,895		
	f Patent and Publications Cited by Applicant everal sheets if necessary)	Applicant Scott A. Waldman	et al.		
J.	epartment of Commerce t and Trademark Office	Filing Date 09/05/2003	Group 51614		
ОТНЕ	R DOCUMENTS (Including Autho	r, Title, Date, Pertine	nt Pages, Etc.)		
AK	Coperhave et al., "The Digestive Sys Edition, Williams and Wilkens, Balti	-	· · · · · · · · · · · · · · · · · · ·		
AL	Cull et al., "Screening for receptor lig the C terminus of the <i>lac</i> repressor",		<del>-</del> -		
AM	Francis et al., Peptide Vaccines Based on Enhanced Immunogenicity of Peptide Epitopes Presented with T-Cell Determinants or Hepatitis B Core Protein", <i>Methods in Enzymol.</i> , <b>1989</b> , <i>178</i> , 659-676				
AN	Gallop et al., "Applications of Combinatorial Technologies to Drug Discovery. 1. Background and Peptide Combinatorial Libraries", J. Med. Chem., 1994, 37(9), 1233-1251				
AO	Gordon et al., "Applications of Coml Combinatorial Organic Synthesis, Li Directions", J. Med Chem., 1994, 37	brary Screening Strate			
AP	Hammer et al., "Promiscuous and Allele-Specific Anchors in HLA-DR-Binding Peptides", Cell, 1993, 74, 197-203				
AQ	Haralambidis et al., "The Solid Phase Synthesis of Oligonucleotides Containing a 3'- Peptide Moiety", <i>Tetra. Letts.</i> , <b>1987</b> , 28(43), 5199-5202				
AR	Helen et al., "Specific regulation of gene expression by antisense, sense, and antigene nucleic acids", <i>Biochem. Biophys. Acta</i> , <b>1990</b> , <i>1049</i> , 99-125				
AS	Kniazev et al., "Comprehensive Characteristics of Alterations of HER-2/ERBB-2, HER-1/ERBB-1, HRAS-1, and C-MYC Oncogenes, and of p53 and RBI Antioncogenes, and also of Deletions of Loci of Chromosome 17 in Colorectal Carcinomas", Mol. Biol., 1992, 26(5), 1-15				
AT Kwok et al., "Calculation of radiation doses for nonuniformly distributed β and $\gamma$ radionuclides in soft tissue", Med. Phys., 1985, 12(4), 405-412					
EXAMINER		DATE CONSIDER	ED		

Form	PTO-1449 Modified	Docket No. 08321-0152 CT1	Serial No. 10/656,895	
	f Patent and Publications Cited by Applicant everal sheets if necessary)	Applicant Scott A. Waldman	ı et al.	
	Department of Commerce and Trademark Office	Filing Date 09/05/2003	Group 1614	
ОТНЕ	R DOCUMENTS (Including Au	thor, Title, Date, Pertin	ent Pages, Etc.)	
AV	Magerstadt, M., Antibody Conjug Raton, USA, 1991, 110-152	rates and Malignant Dise	ease, CRC Press, Boca	
AW	Melani et al., "Inhibition of proliferation by <i>c-myb</i> antisense oligodeoxynucleotides in colon adenocarcinoma cell lines that express <i>c-myb</i> ", Cancer Res., 1991, 51(11), 2897-2901			
AX	Miller et al., "The Induction of Hapten-Specific T Cell Tolerance by Using Hapten-Modified Lymphoid Cells", J. Immunol., 1976, 117(5:1), 1519-1526			
AY	Nielsen et al., "Sequence-specific transcription arrest by peptide nucleic acid bound to the DNA template strand", <i>Gene</i> , 1994, 149, 139-145			
AZ	Osteresh et al., "Libraries from libraries": Chemical transformation of combinatorial libraries to extend the range and repertoire of chemical diversity", <i>Proc. Natl. Acad. Sci. USA</i> , <b>1994</b> , <i>91</i> , 11138-11142			
BA	Ohlmeyer et al., "Complex synthetic chemical libraries indexed with molecular tags", Proc. Natl. Acad. Sci USA, 1993, 90, 10922-10926			
ВВ	Ramsey et al., "Myb expression is higher in malignant human colonic carcinoma and premalignant adenomatous polyps than in normal mucosa", Cell Growth & Different., 1992, 3(10), 723-730			
ВС	Rodriguez-Alfageme et al., "Suppression of deregulated c-MYC expression in human colon carcinoma cells by chromosome 5 transfer", <i>Proc. Natl. Acad. Sci. USA</i> , 1992, 89(4), 1482-1486			
BD	Ruggeri et al., "Inhibition of platelet function with synthetic peptides designed to be high-affinity antagonists of fibrinogen binding to platelets", <i>Proc. Natl. Acad. Sci. USA</i> , 1986, 83, 5708-5712			
BE	Sad et al., "Bypass of carrier-indepetitione", Immunology, 1992, 76,		pression using a T-helper	
EXAMINER	,	DATE CONSIDE	RED	

Form	PTO-1449 Modified	Docket No. 08321-0152 CT1	Serial No. 10/656,895		
	f Patent and Publications Cited by Applicant everal sheets if necessary)	Applicant Scott A. Waldman	et al.		
	Pepartment of Commerce t and Trademark Office	Filing Date 09/05/2003	Group 1614		
ОТНЕ	R DOCUMENTS (Including Auth	or, Title, Date, Pertin	ent Pages, Etc.)		
BF	de Sauvage et al., "Primary Structure Escherichia coli Heat-stable Enterotox				
BG	Sepetov et al., "Library of libraries: design and screening of "pharmacog 92, 5426-5430				
ВН	Sizeland et al., "Antisense transforming growth factor alpha oligonucleotides inhibit autocrine stimulated proliferation of a colon carcinoma cell line", <i>Mol. Biol. Cell</i> , 1992, 3(11), 1235-1243				
ВІ	Smith et al., "A ribonuclease S-peptide antagonist discovered with a bacteriophage display library", Gene, 1993, 128, 37-42				
ВЈ	Takekawa et al., "Chromosomal localization of the protein tyrosine phosphatase G1 gene and characterization of the aberrant transcripts in human colon cancer cells", FEBS Letts., 1994, 339(3), 222-228				
ВК	Tanaka et al., "Suppression of tumorigenicity in human colon carcinoma cells by introduction of normal chromosome 1p36 region", Oncogene, 1993, 8(8), 2253-2258				
BL	Toribara et al., "Screening for color 861-867	ectal cancer", New Eng	z. J. Med., 1995, 33.2(13),		
ВМ	Ullrich et al., "Insulin-like growth factor I receptor primary structure: comparison with insulin receptor suggests structural determinants that define functional specificity", EMBO J., 1986, 5(10), 2503-2512				
BN	Waldman et al., "Immunoaffinity Purification of Soluble Guanylyl Cyclase", Methods in Enzymol., 1991, 195, 391-396				
ВО	Wang et al., "Application of the Multipin Peptide Synthesis Technique for Peptide Receptor Binding Studies: Substance P as a Model System", Bioorg. Med. Chem. Lett., 1993, 3(3), 447-450				
EXAMINER		DATE CONSIDER	RED		

Form	Form PTO-1449 Modified		Serial No. 10/656,895		
List of Patent and Publications Cited by Applicant (Use several sheets if necessary)		Applicant Scott A. Waldman et al.			
1	epartment of Commerce t and Trademark Office	Filing Date 09/05/2003	Group 1614		
ОТНЕ	R DOCUMENTS (Including Author	r, Title, Date, Pertine	nt Pages, Etc.)		
ВР	Wessels et al., "Radionuclide selection radiolabeled tumor associated antibodies."	·	•		
BQ	Wide, "Solid Phase Antigen-Antibod (ed.), E. & S. Livingstone, Edinburgh		ne Assay Method, Kirkham		
BR	Wu et al., "Evidence for ed gene deli Biochem., 1988, 27, 887-892	very to Hep G2 hepato	ma cells in vitro",		
BS	Yokozaki et al., "An antisense oligodeoxynucleotide that depletes RI alpha subunit of cyclic AMP-dependent protein kinase induces growth inhibition in human cancer cells", Cancer Res., 1993, 53(4), 868-872				
ВТ	Zuckermann et al., "Discovery of Nanomolar Ligands for 7-Transmembrane G-Protein-Coupled Receptors from a Diverse N-(Substituted)glycine Peptoid Library", J. Med. Chem., 1994, 37, 2678-2685				
BU	Almenoff, et al., "Ligand-based Histochemical Localization and Capture of Cells Expressing Heat-Stable Enterotoxin Receptors", Mol. Microbiol., 1993, 8, 865-873				
BV	Chelly, J. et al., "Illegitimate transcription: Transcription of any gene in any cell type", <i>Proc. Natl. Acad. Sci. USA</i> , 1989, 86, 2617-2621				
BW	Chelly, J. et al., "Illegitimate Transcription: Application to the Analysis of Truncated Transcripts of the Dystrophin Gene in Nonmuscle Cultured Cells from Duchenne and Becker Patients", J. Clin. Invest., 1991, 88(4), 1161-1166				
BX	Cohen, M., et al., "Receptors for <i>Escherichia coli</i> Heat Stable Enterotoxin in Human Intestine and in a Human Intestinal Cell Line (Caco-2)", <i>J. Cellular Physiol.</i> , 1993, 156, 138-144				
ВУ	Cooper, D.N. et al., "Ectopic (Illegitimate) Transcription: New Possibilities for the Analysis and Diagnosis of Human Genetic Disease", Ann. Med., 1994, 26(1), 9-14				
BZ	de Sauvage, F., et al., "Primary Structure and Functional Expression of the Human Receptor for Escherichia coli Heat-stable Enterotoxin", J. Biol. Chem., 1991, 266, 17912-17918				
CA	Drewett, J. et al., "The Family of Guanylyl Cyclase Receptors and Their Ligands", Endocrine Reviews, 1994, 15(2), 135-162				
EXAMINER		DATE CONSIDER	ED		

Forr	n PTO-1449 Modified	Docket No. 08321-0152 CT1	Serial No. 10/656,895			
	of Patent and Publications Cited by Applicant several sheets if necessary)	Applicant Scott A. Waldman et al.				
4	Department of Commerce ent and Trademark Office	Filing Date 09/05/2003	Group			
	ER DOCUMENTS (Including Author		<u> </u>			
СВ	Forte, L., et al., "Receptors and cGM in Opossum Kidney", Am. J. Physio	•				
CC	Forte, L., et al., "Escherichia coli En Kidney, Intestine, and Testis", Am.	•	-			
CD	Guarino, A., et al., "T <sup>84</sup> Cell Recept Escherichia coli Heat-Stable Toxin' 16): G775-780, <b>1987</b>		-			
CE	Enterotoxin of Escherichia coli: Stu	Guerrant, R., et al., "Activation of Intestinal Guanylate Cyclase by Heat-Stable Enterotoxin of <i>Escherichia coli</i> : Studies of tissue Specificity, Potential Receptors, and Intermediates", <i>J. Infect. Dis.</i> , 1980, 142(2), 220-228				
CF	Stable Toxin Receptors and Particulate Gu	Hakki, et al., "Solubilization and Characterization of Functionally Coupled Escherichia coli Heat- Stable Toxin Receptors and Particulate Guanylate Cyclase Associated with the Cytoskeleton Compartment of Intestinal Membranes", Int. J. Biochem., 1993, 25, 557-566				
CG	Circulating Tumor Cells Using Imn	Hardingham, J.E., et al., "Immunobead-PCR: A Technique for the Detection of Circulating Tumor Cells Using Immunomagnetic Beads and the Polymerase Chain Reaction", Cancer Research, 1993, 53, 3455-3458				
СН	Hugues, et al., "Identification and C Receptors for Escherichia coli Heat Biochemistry, 1991, 30, 10738-1074	-Stable Enterotoxin in				
· CI	Kaplan, J.C. et al., "Illegitimate tran Human Mutation, 1992, 1(5), 357-3	<del>-</del>	study of inherited disease",			
CJ	Negrier, C. et al., "Illegitimate transcription: its use for studying genetic abnormalities in lymphoblastoid cells from patients with Glanzmann thrombasthenia", <i>British J. Haematology</i> , <b>1998</b> , <i>100(1)</i> , 33-39					
СК	Thompson, M.R., "Escherichia coli Heat-Stable Enterotoxins and Their Receptors", Pathol. Immunopathol. Res., 1987, 6, 103-116					
CL	Zippelius, A. et al., "Limitations of Reverse-Transcriptase Polymerase Chain Reaction Analyses for Detection of Micrometastatic Epithelial Cancer Cells in Bone Marrow", J. Clin. Oncology, 1997, 15(7), 2701-2708					
EXAMINER		DATE CONSIDER	ED			

	Form PTO-1449 Modified			Docket No. 08321-0152 CT1	Serial No		
	C	Patent and Publica Cited by Applicant veral sheets if neces		Applicant			
	U.S. Department of Commerce Patent and Trademark Office			Filing Date 09/05/2003	Group 1614		
		Ţ	J. S. PATENT D	OCUMENTS	···	· · · · · · · · · · · · · · · · · · ·	
Examiner Initial		Document No.	Date	Name .	Class	Subclass	
	CM	4,022,878	05/10/77	Gross	424	1.5	
·	CN	4,329,281	05/11/82	Christenson et al.	260	112.B	
	СО	4,526,716	07/02/85	Stevens	260	112.5 R	
	CP.	4,584,268	04/22/86	Ceriani et al.	436	504	
	CQ	4,601,896	07/22/86	Nugent	424	36	
	CR	4,683,195	07/28/87	Mullis et al.	435	6	
	CS	4,683,202	07/28/87	Mullis	435	91	
	CT	4,729,893	03/08/88	Letcher et al.	424	98	
	CU	4,736,866	04/12/88	Leder et al.	800	1	
	CV	4,849,227	07/18/89	Cho	424	498	
	CW	4,873,191	10/10/89	Wagner et al.	435	172.3	
	CX	4,945,050	07/31/90	Sanford et al.	435	172.1	
	CY	4,963,263	10/16/90	Kauvar	210	635	
•	CZ	4,965,188	10/23/90	Mullis et al.	435	6	
	DA	5,017,487	05/21/91	Stunnenberg et al.	435	172.3	
	DB	5,037,645	08/06/91	Strahilevitz	424	85.8	
	DC	5,075,216	12/24/91	Innis et al.	435	6	
	DD	5,112,606	05/12/92	Shiosaka et al.	530	389.2	
-	DE	5,133,866	07/28/92	Kauvar	210	635	
EXAMINI	ER			DATE CONSIDE	RED		

Form PTO-1449 Modified			ed	Docket No. 08321-0152 CT1	Serial No	
	List of Patent and Publications Cited by Applicant (Use several sheets if necessary) U.S. Department of Commerce Patent and Trademark Office			Applicant Scott A. Waldman et al.		
				Filing Date 09/05/2003	Group 1614	
	·	U. S	. PATENT DO	CUMENTS		
Examiner Initial		Document No.	Date	Name	Class	Subclass
	DF	5,143,854	09/01/92	Pirrung et al.	436	518
	DG	5,160,723	11/03/92	Welt, et al.	424	1.1
	DH	5,217,869	06/08/93	Kauvar	435	7.9
	DI	5,221,736	06/22/93	Coolidge et al.	536	25.31
	DJ	5,223,409	06/29/93	Ladner et al.	435	69.7
	DK	5,237,051	08/17/93	Garbers et al.	530	350
	DL	5,252,743	10/12/93	Barrett et al.	548	303.7
	DM	5,270,170	12/14/93	Schatz et al.	435	7.37
	DN	5,271,961	12/21/93	Mathiowitz et al.	427	213.31
	DO	5,288,514	02/22/94	Ellman	427	2 .
	DP	5,324,483	06/28/94	Cody et al.	422	131
	DQ	5,330,892	07/19/94	Vogelstein et al.	435	6
	DR	5,338,665	08/16/94	Schatz et al.	435	6
	DS	5,340,474	08/23/94	Kauvar	210	198.2
	DT	5,350,741	09/27/94	Takada	514	3
	DU	5,352,775	10/04/94	Albertsen et al.	536	23.1
	DV	5,366,862	11/22/94	Venton et al.	435	7.1
	DW	5,384,261	01/24/95	Winkler et al.	436	518
	DX	5,395,750	03/07/95	Dillon et al.	435	5
	DY	5,399,347	03/21/95	Trentham et al.	424	184.1
EXAMINE	R			DATE CONSIDER	RED	

Form PTO-1449 Modified  List of Patent and Publications Cited by Applicant (Use several sheets if necessary)				Docket No. 08321-0152 CT1	Serial No. 10/656	
				Applicant Scott A. Waldman et al.		
U.S. Department of Commerce Patent and Trademark Office			Filing Date 09/05/2003	1.		
		U.	S. PATENT D	OCUMENTS		
Examiner Initial		Document No.	Name	Class	Subclass	
	DZ	5,405,783	04/11/95	Pirrung et al.	436	518
	EA	5,412,087	05/02/95	McGall et al.	536	24.3
	EB	5,420,328	05/30/95	Campbell	558	110
	EC ·	5,424,186	06/13/95	Fodor et al.	435	6
	ED	5,430,138	07/04/95	Urdea et al.	536	26.8
	EE	5,437,977	08/01/95	Segev	435	6
	EF	5,597,909	01/28/97	Urdea et al.	536	24.3
	EG	5,731,159	03/24/98	Waldman	435	7.23
	ЕН	5,518,888	05/21/96	Waldman	435	7.23
,	EI	5,601,990	02/11/97	Waldman	435	7.23
	EJ	5,928,873	07/27/99	Waldman	435	6
	EK	5,962,220	10/05/99	Waldman	435	6
		FOR	EIGN PATEN	T DOCUMENTS		
Examiner Initial		Document No.	Date	Country	YES T	ranslation NO
	EL	WO 95/11694	05/04/95	PCT		
	EM	WO 97/42220	11/13/97	PCT		·
· .	EN	WO 97/42506	11/13/97	PCT		
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Forn	1 PTO-1449 Modified	Docket No. 08321-0152 CT1	Serial No. 10/656,895			
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	Department of Commerce nt and Trademark Office	Filing Date 09/05/2003	Group 1614			
ОТНІ	ER DOCUMENTS (Including A	uthor, Title, Date, Pertin	ent Pages, Etc.)			
119	Carrithers, S.L. Ph.D., et al. "Es Novel Marker for Colorectal Tu 39(2), 171-181	cherichia Coli Heat -Stabl mors", Diseases of the Co	e Enterotoxin Receptors: A lon and Rectum, 1996,			
120	Rousset, E. et al., "Bacterial Ent 31(4), 413-435 (Abstract Provid	erotoxin Receptors", Veter ed)	rinary Research, 2000,			
121	S. Schulz, Ph.D., "A Splice Vari Clinical Pharmacology & Thera	S. Schulz, Ph.D., "A Splice Variant of the Heat-Stable Enterotoxin Receptor", Clinical Pharmacology & Therapeutics, 1998, 63(2), 226				
122	de Sauvage et al. (Accessio	n #M73489, 1991)				
123	Singh et al. (Accession #S	57551, 1991)				
124	Skolnick J, et al. TRENDS	BIOTECH 2000; 18(1):	34-39			
125	Database GENBANK, Accessio	n No. ACO10106, 19 Se	eptember 2000			
126	126 Database GENBANK, Accession No. AL359386, 20 January 2001					
	·					
EXAMINER		DATE CONSIDER	ED			